UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JULIANNE NUNNELLY and MATTHEW SHANKS

Plaintiffs,

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

1:20-cv-11401-PBS

Leave to file granted on 06/07/2024

DEFENDANT REGENERON'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO DISMISS

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Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron"), respectfully submits this Memorandum of Law in support of its Motion to Dismiss the complaints filed by the United States and Intervening States Colorado, Georgia, Michigan, North Carolina, Texas, and Washington.

PRELIMINARY STATEMENT

Every day, millions of businesses charge their customers a single cash-or-credit price and thus allow some customers to buy products with a credit card (and potentially obtain rewards or cash-back) without paying an upcharge. Plaintiffs seek to turn this ordinary and unobjectionable practice into a False Claims Act ("FCA") violation punishable by colossal fines and damages, all without anything approaching clear notice to Regeneron. Plaintiffs' novel theory is not only incompatible with the text of the relevant statute and regulations, but divorced from reality.

The facts are straightforward. Regeneron manufactures EYLEA® (aflibercept) Injection 2mg ("EYLEA"), a prescription drug used to treat the leading cause of blindness in elderly Americans, and sells it through specialty distributors. Those distributors, like millions of other businesses, charge their customers (here, ophthalmologists) a single price regardless of whether they pay by cash or credit—even though financial institutions charge the distributors to process credit card purchases of EYLEA, just as they do for credit card purchases of groceries, clothes, or books. Regeneron reimburses distributors for the cost of those transaction fees.

All of this is commonplace, unobjectionable, and if anything produces a lower Average Sales Price ("ASP"). Yet Plaintiffs now make the remarkable claim that Regeneron is bilking the federal government and six states by failing to treat these reimbursed credit card processing fees as some kind of cash discount that must be subtracted in calculating EYLEA's ASP. The problems with Plaintiffs' theory are legion.

First, Plaintiffs' theory is foreclosed by the plain text of the ASP statute. Congress instructed pharmaceutical manufacturers to start with the regular sales price of a prescription drug

product and then subtract six enumerated "price concessions": (1) "volume discounts," (2) "prompt pay discounts," (3) "cash discounts," (4) "free goods that are contingent on any purchase requirement," (5) "chargebacks," and (6) "rebates." 42 U.S.C. § 1395w-3a(c)(3). Simply allowing the purchaser to pay with a credit card is not on that list, nor is reimbursing distributors for the actual cost of processing credit card transactions. That makes sense, as both simply ensure that doctors pay the same price regardless of whether they pay by cash or credit. That should be the end of the matter.

Indeed, Plaintiffs do not contend that simply charging physicians a single price regardless of whether they pay with cash or credit (and regardless of whether the manufacturer or distributor shoulders the processing fees for credit card payments) amounts to a price concession. Nor could they. Charging one price—regardless of payment method—is the opposite of giving some purchasers a discount or price concession. Plaintiffs' theory instead is that Regeneron's practice of reimbursing its distributors for the actual costs financial institutions charge to process credit card transactions somehow changes the calculus. But paying distributors back for expenses they actually incur in getting Regeneron's product to Regeneron's customers (and that Regeneron would bear directly if it sold its products directly) is obviously not a price concession.

That points to a second, and related (but independent) flaw with Plaintiffs' theory: Federal regulations are explicit that reimbursements for "bona fide services fees" need not be subtracted from ASP, 42 C.F.R. § 414.804(a)(2)(ii), and the fees that financial institutions charge to process credit card transactions fit the definition of a "bona fide service fee" to a T. Plaintiffs do not (and cannot) deny that (i) financial institutions perform a valuable service when they process credit card transactions; (ii) Regeneron's practice is to reimburse distributors for the actual costs financial institutions charge to process credit card transactions; (iii) Regeneron would pay the fee directly

to the financial institutions if it sold EYLEA directly to physicians; or (iv) as a result of Regeneron's practice, the fees are not passed on to the physicians. *See id.* § 414.802 (defining "Bona fide service fees"). Nor do Plaintiffs have any way of explaining why credit card processing fees should be treated differently from, say, shipping fees, which distributors likewise incur as part of distribution and manufacturers likewise reimburse. That is because there is no reason to treat them differently. Both are textbook "bona fide services fees," which "are not considered price concessions" and thus need not be included in calculating ASP. *Id.* § 414.804(a)(2)(ii).

Third, even apart from whether Regeneron's treatment of reimbursed credit card processing fees represents the best interpretation of the ASP statute and the bona fide service fee regulations (it does), it is plainly reasonable. In this context, where the government has asked for "reasonable" judgments in calculating ASP, claims reflecting a reasonable approach cannot be deemed false. Throughout society, sellers and purchasers routinely treat the single stated cash-or-credit price as the relevant price for a product without accounting for potential surcharges or any rewards or cash-back consumers may receive as a result of purchasing by credit card. Similarly, countless employees and suppliers seek reimbursement for the single cash-or-credit price paid without accounting for rewards or cash-back or worrying about whether any processing fees were reimbursed. There is nothing false or fraudulent about those commonplace practices. To the contrary, treating the actual price paid with a credit card as the relevant price is perfectly reasonable.

That dooms Plaintiffs' allegations of falsity. Under First Circuit precedent, "statements as to conclusions about which reasonable minds may differ cannot be false" as a matter of law. *United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 87 (1st Cir. 2012) (citation omitted). That rule governs false-statement cases generally, and it applies *a fortiori* here. Indeed,

this is just about the last context in which the government should be allowed to punish private parties for adopting a reasonable interpretation of the relevant law. Industry has repeatedly asked the government for additional guidance on what constitutes a bona fide service fee, and the Centers for Medicare and Medicaid Services ("CMS") and the Department of Health and Human Services Office of the Inspector General ("HHS-OIG") have both acknowledged the lack of clarity on that issue and the need for further guidance. Yet CMS has steadfastly refused to offer clarity or guidance. Instead, it has instructed manufacturers simply to make "reasonable assumptions" in calculating ASP. Having provided an admonition to act reasonably in lieu of specific guidance, the government cannot turn around and seek massive recoveries from companies that made the same reasonable assumptions as most merchants and consumers about there being a single cash-or-credit price.

Fourth, even assuming Plaintiffs could allege that Regeneron is calculating ASP incorrectly (it is not), Plaintiffs do not allege falsity *in any claim for payment presented to the government*—a basic requirement for any FCA violation under 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B). It is well established that "underlying fraudulent conduct … does not in and of itself establish the 'false or fraudulent claim' required for liability under both §§ 3729(a)(1)(A) and (B)." *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34, 53 (D. Mass. 2014). Rather, "for a false statement to be actionable under either subsection of the FCA, it must be made as part of a false or fraudulent claim." *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 196 (4th Cir. 2018). And Plaintiffs do not allege that anything in any actual request for reimbursement for EYLEA—the only claims for payment at issue here—is false or fraudulent in any way (because nothing is).

Finally, Plaintiffs do not plausibly plead that Regeneron acted with scienter, their wholly duplicative unjust enrichment claims fail as a matter of law, and the claims based on analogous state-law false claims prohibitions suffer the same defects as the federal FCA claims.

The complaints here fail at every turn. The Court should dismiss them with prejudice.

BACKGROUND

A. Factual Background

Regeneron was founded in 1988 to develop new medicines for people with serious and rare diseases. Over the ensuing decades, Regeneron's leadership team—comprised of its founding scientists, industry experts, and Nobel laureates—has consistently pushed the boundaries of scientific excellence and discovery with a shared commitment to transforming lives for the better. The company spent 20 years and over a billion dollars conducting research before bringing its first drug to market in 2008. Regeneron has developed twelve FDA-approved medicines, while continually reinvesting in the development of innovative and urgently needed drugs.

Regeneron launched EYLEA in 2011. ECF No. 58 ("Compl.") ¶ 42. EYLEA is a prescription pharmaceutical approved by the Food and Drug Administration ("FDA") to treat serious eye conditions, including the leading cause of blindness in the elderly.[1] *Id*. ¶¶ 41-42. Ophthalmologists administer EYLEA in their offices by injecting it periodically into a patient's eye. *Id.* ¶ 3. Regeneron does not sell EYLEA directly to physicians. Instead, it contracts with specialty distributors, which in turn sell EYLEA to ophthalmology practices. *Id.* ¶¶ 46-47.

Regeneron's distribution agreements require its distributors to perform or contract out specific services attendant to distribution. *Id.* Regeneron pays for most of these services—

[1] *Regeneron Announces FDA Approval of EYLEA (Aflibercept) Injection for The Treatment of Wet Age-Related Macular Degeneration: Corrected*, Regeneron Pharms., Inc. (Nov. 18, 2011), https://tinyurl.com/EYLEA-FDA-Approval.

including product storage, order processing, packing supplies, standard shipping, invoice processing, and return processing—through a fixed fee or a set percentage of EYLEA's price. Compl. Ex. 2 at 28-34.[2] Regeneron pays for other services—including nonstandard shipping and credit card processing—at those services' cost. *See id.* at 31-32. The distributors invoice Regeneron for each fee separately incurred. *See, e.g.*, Compl. Ex. 14 at 3 (itemized invoice with separate entries for distribution fees ("Serv Fees"), credit card processing fees, and shipping fees).

Regeneron's distributors charge doctors the same price for EYLEA whether they pay in cash or with a credit card. Compl. ¶ 6. But processing credit card transactions is not costless; it is a complicated endeavor, and financial institutions charge for the services they perform. As the Federal Deposit Insurance Corporation ("FDIC") has explained, credit card "*processing* is a separate and distinct line of business from credit card *issuing*." FDIC, Div. of Supervision & Consumer Prot., *Risk Management Examination Manual for Credit Card Activities*, ch. XIX, at 164 (Mar. 2007), https://tinyurl.com/442bbcvv ("FDIC Manual") (emphases added). It involves a 13-step process, including "gathering of sales information from the merchant, obtaining authorization for the transaction, collecting funds from the issuing bank, and reimbursing the merchant." *Id.* Financial institutions charge to cover the cost of this service and to account for the "risk posed by the merchant." *Id.* at 174. The fee is usually one to three percent of the purchase price, although the precise amount varies depending upon, *inter alia*, the specific card a customer uses. *See* U.S. Gov't Accountability Off., GAO-10-45, *Credit Cards: Rising Interchange Fees Have Increased Costs for Merchants, but Options for Reducing Fees Pose Challenges* 9-10, 17 (Nov. 2009).

[2] Exhibit page numbers refer to the .pdf page numbers, with each exhibit's cover page as page 1.

Here, as in many other settings, the fee that financial institutions charge to process credit card transactions is paid by the seller (i.e., distributor), not the buyer (i.e., doctor). Compl. ¶ 6. Doctors thus pay the same price for EYLEA no matter how they pay (cash, check, credit card, etc.). *See id.* Doctors who pay with a credit card neither receive a discount nor pay a surcharge.[3]

B. Legal Background

1. The ASP Statute

EYLEA is a "buy-and-bill" drug, which means doctors typically buy it from a distributor and then bill Medicare, Medicaid, or private insurance only after administering it to a patient. Compl. ¶¶ 4, 22-23. In general, Medicare does not reimburse physicians based on the amount they paid for a drug. Rather, under the Medicare Modernization Act, Medicare determines reimbursement amounts for prescription drugs via a statutory formula based on Average Sales Price, or "ASP." *See* 42 U.S.C. §§ 1395w-4(a)(1), 1395u(o)(1), 1395x(s)(2)(A), 1395w-3a; 42 C.F.R. § 414.904. (The reimbursement amount is set by statute, and is typically 106% of ASP. 42 U.S.C. §§ 1395w-4(a)(1), 1395w-3a(b)(1)(B).)

ASP is the average sales price of a drug, minus specific "price concessions" enumerated by Congress. The starting place for calculating a given drug's ASP is straightforward: The statute

[3] This is in line with the laws of several states, including Massachusetts, which prohibit merchants from imposing a surcharge on customers who use a credit card. *See* Mass. Gen. Laws ch. 140D, § 28A; Conn. Gen. Stat. § 42-133ff; Me. Rev. Stat. tit. 9-A, § 8-509; 10 L.P.R.A. § 11. New York, Colorado, and Utah also prohibited this practice for part of the relevant period. *See* N.Y. Gen. Bus. Law § 518 (amended by 2023 N.Y. Sess. Laws ch. 723 (A2672-B), effective Feb. 11, 2024); Colo. Rev. Stat. 5-2-212 (amended by 2021 Colo. Sess. Laws 3404, effective July 1, 2022); Utah Code Ann. § 13-38a-301 (repealed pursuant to Utah Code Ann. § 63i-1-213, effective June 30, 2014). Several other states, including California, Florida, Kansas, Oklahoma, and Texas, had bans that have been limited or vacated over the past decade but were in effect for some portion of the relevant period. *See Italian Colors Rest. v. Becerra*, 878 F.3d 1165 (9th Cir. 2018); *Dana's R.R. Supply v. Att'y Gen.*, 807 F.3d 1235 (11th Cir. 2015), *denying reh'g en banc*, 809 F.3d 1282 (11th Cir. 2016); *CardX, LLC v. Schmidt*, 522 F. Supp. 3d 929 (D. Kan. 2021); Att'y Gen. Op. No. 2019-12, 2019 WL 7046026, at *1 (Okla. A.G. Dec. 17, 2019); *Rowell v. Paxton*, 336 F. Supp. 3d 724 (W.D. Tex. 2018).

directs manufacturers to begin by dividing "(A) the manufacturer's sales to all purchasers … in the United States for such drug … in the calendar quarter," by "(B) the total number of such units of such drug … sold by the manufacturer in such quarter." 42 U.S.C. § 1395w-3a(c)(1). From there, the calculation gets more complex, as certain types of "sales" (not relevant here) "shall be excluded" from the "calculati[on]." *Id.* § 1395w-3a(c)(2). Finally, manufacturers "shall include" (i.e., subtract from the numerator) "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and [most] rebates." *Id.* § 1395w-3a(c)(3).

2. The ASP Regulatory Regime—And CMS's Lack Of Guidance

Congress authorizes HHS to add via rulemaking additional "price concessions" that manufacturers must include in a drug's ASP. *Id.* But HHS (through CMS, to which HHS delegated that authority, *see* 66 Fed. Reg. 35,437 (July 5, 2001)) has never used that authority. Stated differently, while the Executive Branch *can* expand the list of price concessions that affect ASP, it has declined to do so thus far. In fact, it has done the opposite: In its only relevant rule, CMS has specified that "bona fide services fees" should *not* be included in ASP, even if they could arguably be characterized as one of the six enumerated concessions. 42 C.F.R. § 414.804(a)(2)(ii); *see also id.* § 414.802 (defining "bona fide service fees").

While that much is clear, CMS has been reticent about providing additional guidance. "Given the complexities of the pharmaceutical marketplace," manufacturers have long found "it difficult to determine how to treat certain sales practices when calculating ASPs." HHS-OIG, OEI-BL-21-00330, *Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices* 4 (Dec. 2022), https://oig.hhs.gov/oei/reports/OEI-BL-21-00330.pdf ("2022 HHS-OIG Report"). Manufacturers have thus consistently asked CMS for additional clarity. They have not been alone in prodding CMS for direction on this issue: HHS-OIG has not

only acknowledged the "lack of clear guidance from CMS on issues related to the treatment of sales and discounts that affect ASP calculations," but recommended that CMS issue further guidance to avoid "inconsistencies in manufacturer ASP calculations." *Id.* at 11, 15. Even CMS itself has acknowledged that additional "guidance in the ASP context is warranted to provide for greater consistency in ASP reporting across manufacturers and to enhance the accuracy of the ASP payment system." 72 Fed. Reg. 66,222, 66,257 (Nov. 27, 2007); *see also* 2022 HHS-OIG Report at 16 ("CMS concurred with OIG's recommendation.").

But despite industry's pleas, HHS-OIG's recommendations, and its own recognition that calculating ASP is often a complicated exercise, CMS has declined to provide clarity. As relevant here, CMS not only has refused to issue guidance identifying the types of service fee arrangements that would qualify as presumptively bona fide (or not), *see, e.g.*, 71 Fed. Reg. 69,624, 69,668 (Dec. 1, 2006) (declining manufacturer requests to establish such a list), but has even rejected calls to provide *examples* of bona fide service fees. In particular, CMS has stated that, "because of the complexities of the marketplace," providing a list would just "raise[] further questions as to why some examples were included and some excluded from that list." 72 Fed. Reg. 39,142, 39,184 (July 17, 2007). According to CMS, it has declined to provide such a list "*to avoid inadvertently limiting the scope of what could constitute a bona fide service*." 71 Fed. Reg. at 69,668 (emphasis added).

Instead of providing clarity, CMS has provided assurances that manufacturers will not be punished for making reasonable judgment calls—instructing manufacturers that, "[i]n the absence of specific guidance" from Congress or the agency, they "may make reasonable assumptions in [their] calculations of [ASP]." *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 71 n.24 (D. Mass. 2011) (quoting CMS, *ASP Reporting Requirements Questions and Answers*

2257 (document since removed from CMS website)); *accord, e.g.*, 71 Fed. Reg. 48,982, 49,000 (Aug. 22, 2006) ("[I]n the absence of specific guidance," the "manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Social Security Act, Federal regulations, and its customary business practices."); 71 Fed. Reg. at 69,669 (making the same statement in response to an industry request for clarification on how to treat fees paid by manufacturers to pharmacy benefit managers under the bona fide service fee regulation); CMS, *CMS Manual System Pub. 100-04: Transmittal No. 1423, Medicare Claims Processing* 6 (Feb. 1, 2008) (similar).

As a result of CMS's failure to issue meaningful guidance and its attendant decision to direct manufacturers "to make reasonable assumptions" about ASP "in the absence of specific guidance," HHS-OIG recently acknowledged that its "ability to identify noncompliance in price reporting is limited." 2022 HHS-OIG Report at 3; *see also id.* at 11 (noting that "CMS has published comparatively fewer regulations and less overall guidance regarding the calculation of ASPs used in Medicare than regarding the AMPs and best prices (BPs) used in Medicaid" and that, "[a]s a result, manufacturers say they must rely on reasonable assumptions to a much greater extent when calculating ASPs than when calculating other payment benchmarks, thus creating the potential for inconsistent ASP calculations across manufacturers and products").

3. Manufacturers' Quarterly ASP Submissions

CMS requires manufacturers to submit quarterly ASP reports that include the Manufacturer's ASP, Number of ASP Units, and Wholesale Acquisition Cost ("WAC") for each Medicare drug they manufacture. 42 C.F.R. § 414.804(a)(5); *see* CMS, *Medicare Part B Average Sales Price (ASP) Module: Submitter User Guide, Version 1.0,* § 3.3.1.1.1 (Mar. 15, 2024),

https://tinyurl.com/y7wwu7hk.[4] "Manufacturers may face civil money penalties if they knowingly provide false information about their ASPs [in these reports] or fail to report ASP data within the required timeframe (i.e., within 30 days of the close of a quarter)." 2022 HHS-OIG Report at 4.

Manufacturers' quarterly ASP reports are not requests for payment. As explained above, physicians are the ones who seek reimbursement for Medicare drugs; they separately bill Medicare for reimbursement after they administer EYLEA to a patient. *Supra* p. 7. Manufacturers' quarterly ASP submissions, by contrast, serve merely a reporting function.

Nor are these quarterly submissions treated as gospel. Quite the opposite: Consistent with the conceded lack of clarity or direction from the government on ASP and the bona fide service fee issue, CMS does not require manufacturers to certify that their ASP calculations are perfect. Instead, a manufacturer's CEO, CFO, or direct report must agree only to the following statement:

> I certify that the reported [ASP]s were calculated accurately and that all information and statements made in this submission are true, complete, and current *to the best of my knowledge and belief and are made in good faith*. I understand that information contained in this submission may be used for Medicare reimbursement purposes.

69 Fed. Reg. 17,935, 17,940 (Apr. 6, 2004) (emphasis added); *see also* CMS, *Medicare Part B Drug Average Sales Price (ASP): User Manual, Version 2.0*, § 12.3 (Apr. 15, 2019) (similar). Along with the reasonable assumptions mandate, this limited certification confirms that manufacturers satisfy their legal obligations when they reasonably ("in good faith") calculate and submit ASP.

Regeneron submits quarterly ASP reports to CMS per these requirements. Compl. ¶ 11. Following CMS's limited guidance, Regeneron made reasonable assumptions about how to

[4] Although the system has changed over time, the relevant reporting fields have remained constant. *See* CMS, *Medicare Part B Drug Average Sales Price (ASP): User Manual, Version 2.0*, § 5 (Apr. 15, 2019), https://tinyurl.com/a7su8dxc.

calculate ASP. *See* Compl. Ex. 43 at 10, 25. One of them is relevant here: Working with third-party experts, Regeneron analyzed whether to include credit card processing fees in ASP, and ultimately concluded that it should not. *See* Compl. Ex. 42 at 23, Ex. 43 at 25.

C. Procedural Background

On July 28, 2020, Relators filed a complaint under seal pursuant to the *qui tam* provisions of the FCA. ECF No. 2; *see* 31 U.S.C. § 3730(b) (authorizing "[a]ctions by private persons"). Relators amended their complaint in July 2022. ECF No. 24.

Despite CMS and HHS-OIG's acknowledgement of both the potential complexity of calculating ASP and the lack of specific guidance about which bona fide service fees are exempt, the Justice Department apparently believes the rules of the road are clear enough that it may impose crippling and "essentially punitive" liability on Regeneron. *See Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000). The United States notified the Court on November 27, 2023, of its election to intervene in part and decline in part pursuant to 31 U.S.C. § 3730(b)(4), and filed its complaint on March 28, 2024, bringing FCA claims under 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B) as well as a federal-common-law claim for unjust enrichment. ECF Nos. 44, 58. On June 25, 2024, Colorado, Georgia, Michigan, North Carolina, Texas, and Washington ("Intervening States") partially intervened in this action and filed a consolidated complaint bringing claims under their state-law analogs. ECF No. 128 ("State Compl."). Regeneron now moves to dismiss.

LEGAL STANDARD

Under Rule 8(a)(2), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). Under Rule 9(b), a party alleging fraud must "set forth with particularity the who, what, when, where, and how of the alleged fraud."

Lawton ex rel. United States v. Takeda Pharm. Co, 842 F.3d 125, 130 (1st Cir. 2016) (citation omitted). Because the FCA "penalizes persons who present, or cause to be presented, to the federal government 'a false or fraudulent claim,'" in an FCA case "Rule 9(b) requires both that the circumstances of the alleged fraud *and the claims themselves* be alleged with particularity." *Id.* (quoting 31 U.S.C. § 3729(a)(1)) (emphasis added); *see also id.* ("FCA liability does not attach to violations of federal law or regulations … independent of any false claim." (citation omitted)). Plaintiffs cannot satisfy either standard.

ARGUMENT

I. Neither Charging Doctors A Single Cash-Or-Credit Price Nor Reimbursing Distributors For Actual Processing Fees Constitutes A Price Concession.

Plaintiffs' case fails at the outset because there was no price concession. Doctors paid the same price for EYLEA whether they paid for it in cash or with a credit card.

The FCA imposes liability on a "person" who "knowingly" (A) "presents, or causes to be presented, a false or fraudulent claim for payment or approval" or (B) "makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1). Here, there is no fraud or falsehood. Congress has made clear what "price concessions" manufacturers must include in ASP, and allowing credit card purchases without surcharges is not on the list—meaning Regeneron fully complied with its statutory and regulatory requirements. If the government wants manufacturers to account for the rewards physicians earn by using credit cards in ASP, or wants to prohibit reimbursement of the processing fees distributors incur when they allow doctors to pay for prescription drugs with credit cards, the proper step is a statutory amendment or a CMS rulemaking using its delegated authority—not an FCA case.

The supposed falsehood underlying Plaintiffs' allegations is their claim that, when Regeneron reimbursed the cost of credit card processing fees that its distributors actually incurred,

it somehow converted its single cash-or-credit price into a "price concession" for doctors who purchased EYLEA with credit cards. *See* Compl. ¶¶ 90-132. The problem with that argument is fundamental: The statute is explicit about which "price concessions" reduce ASP—"volume discounts," "prompt pay discounts," "cash discounts," "free goods," "chargebacks," and "rebates"—and allowing doctors to pay a single cash-or-credit price with a credit card is not on the list. 42 U.S.C. § 1395w-3a(c)(3).

Indeed, Plaintiffs do not appear to suggest that simply allowing doctors to pay a single price via credit card constitutes a price concession that requires manufacturers to account for whatever cash-back or travel rewards (if any) the doctors ultimately receive for paying with plastic. Plaintiffs instead seem to argue that it is the practice of reimbursing distributors for the actual costs of processing credit card transactions that somehow creates a price concession. But that hardly remedies the fundamental flaw in Plaintiffs' theory, as reimbursing actual costs for credit card processing fees is not on Congress' list of price concessions. And for good reason, as reimbursing the fees that third-party financial institutions actually charge to process credit card transactions (whether for prescription drugs or pizza) is not a price concession. It is a reimbursement of expenses actually incurred that ensures that buyers pay *the same* price, regardless of whether they pay by cash or credit. Regeneron thus properly calculated EYLEA's ASP, and Plaintiffs' claims should be dismissed for that reason alone. *See Westmoreland*, 812 F. Supp. 2d at 65 (holding that a manufacturer need not include in ASP an alleged price concession that is "not explicitly mentioned in the statute as a type of price concession").

A. Plaintiffs' Theory Flouts The Text And Structure Of The ASP Statute.

We begin with the text of the ASP statute—and because it makes clear that manufacturers need not account for credit card rewards or reimbursement of processing fees in calculating ASP, we can end there. *See Pub. Int. Legal Found., Inc. v. Bellows*, 92 F.4th 36, 45 (1st Cir. 2024)

("[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous." (citation omitted)). Congress directed that "calculating the manufacturer's average sales price" involves three steps: A manufacturer (i) starts with its "sales to all purchasers (excluding [certain] sales [not relevant here])" in the preceding quarter; (ii) subtracts "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, … [most] rebates," and "such … other price concessions" that "the Secretary" has required them to "include" (if any); and then (iii) divides the resulting sum by "the total number of such units" sold in the quarter. 42 U.S.C. § 1395w-3a(c)(1)-(3).

This case concerns the second step. According to Plaintiffs, Regeneron was required to include in ASP the amounts it reimbursed its distributors for credit card processing fees imposed on them by financial institutions. That makes no sense. Neither the convenience of using credit cards nor the costs of reimbursing processing fees actually incurred made Congress' list of enumerated "price concessions" that a manufacturer "shall include" in ASP. *Id.* § 1395w-3a(c)(3). Nor has "the Secretary" (via CMS) required them to be included. *See id.* Understandably so, as neither using credit cards nor reimbursing distributors for fees actually incurred constitutes a price concession, and the combination of the two allowed distributors to charge doctors a single cash-or-credit price, which is the opposite of a cash discount. Regeneron was therefore under no obligation to include either the rewards doctors may have earned from their credit card companies or the credit card processing fees its distributors actually incurred in calculating EYLEA's ASP.

Congress enumerated only six price concessions that manufacturers "shall include." *Id.* Reimbursed credit card processing fees are not among them. And Congress provided a mechanism for adding other price concessions to the list—namely, via rulemaking—that has never been

employed.[5] There is thus no basis for treating reimbursed credit card processing fees as a seventh price concession that manufacturers industry-wide must account for on pain of FCA liability.

Any other conclusion would defy statutory text and structure and usurp Congress's prerogatives. "When a statute limits a thing to be done in a particular mode, it includes a negative of any other mode." *Raleigh & Gaston R.R. Co. v. Reid*, 80 U.S. (13 Wall.) 269, 270 (1871). If Congress wanted manufacturers to include in ASP anything that could conceivably be considered a "price concession," it would have said so. In Medicare Part D,[6] for example, Congress defined "price" to "take into account negotiated price concessions, such as discounts, *direct or indirect subsidies*, rebates, and *direct or indirect remunerations*, for covered part D drugs, and include any dispensing fees for such drugs." 42 U.S.C. § 1395w-102(d)(1)(B) (emphases added). Here, by contrast, Congress did not include broad, catchall categories such as "direct or indirect subsidies" or "direct or indirect remunerations." Rather, it listed six specific categories of price concessions that manufacturers "shall include" in ASP and then created a process for CMS—not DOJ—to add more price concessions to the list. *Id.* § 1395w-3a(c)(3). As a result, manufacturers are under no obligation to include in ASP an alleged price concession that is "not explicitly mentioned in the statute" or any CMS regulation. *Westmoreland*, 812 F. Supp. 2d at 65.

Ultimately, Plaintiffs' contrary theory makes a hash of the careful text Congress enacted. It may well be the case that, when they are not charged a surcharge, some doctors may prefer to

[5] In contrast, CMS has exercised similar statutory authority as to other aspects of the ASP calculation. *See* 42 U.S.C. § 1395w-3a(b)(2)(B) (authorizing Secretary to "establish the unit for a manufacturer to report and methods for counting units"); 70 Fed. Reg. 70,478 (Nov. 21, 2005) (defining unit); 42 U.S.C. § 1395w-3a(c)(5)(A) (authorizing Secretary to "establish a uniform methodology" for estimating lagged data); 69 Fed. Reg. 55,763 (Sept. 16, 2004) (adopting methodology).

[6] In general, Medicare Part D pays for drugs dispensed in the pharmacy setting, and Part B pays for drugs that are physician-administered. *See generally* 42 U.S.C. § 1395w-102(a), (d), (e).

pay with a credit card based on some combination of convenience, cash-back or other rewards, or keeping money in the bank during the payment cycle. But no one—not even Plaintiffs—has suggested that merely charging a single price regardless of payment method (without assessing a surcharge for paying with a credit card) constitutes a price concession when sales are made by manufacturers directly to purchasers. Nor could they, since charging customers a single cash-or-credit price regardless of payment method is the opposite of giving a select subset of customers a price concession. Nor have Plaintiffs suggested that manufacturers must—or even could—account for the varying rewards and benefits doctors receive for using credit cards in transactions with distributors. A manufacturer's decision to reimburse its distributors for the actual costs of processing credit card payments does not transform the credit card purchases into discounts or otherwise constitute a price concession. The reimbursement of costs actually incurred looks nothing like a price concession. That should end the matter.

B. Reimbursing Distributors For Credit Card Processing Fees Is Not Remotely A "Price Concession."

Even if there were some seventh form of price concession that manufacturers must include even in the absence of statutory direction or agency rulemaking, reimbursing distributors for the cost of credit card processing fees would not be it. That is because reimbursing distributors for the actual cost financial institutions charge them to process credit card transactions is not offering a "price concession." *See, e.g.*, *Concession*, Webster's Third New International Dictionary (2002) ("a reduction in price from the current price"); 3 Health Care Law Sourcebook § 447.502 ("discount or rebate"). To the contrary, Regeneron is reimbursing expenses that its distributors actually incur as part of the process of distribution (i.e., getting Regeneron's products to its customers) in order to charge a single price without concessions for cash, credit, check, or wire.

All of the statutorily enumerated categories, by contrast, result in a particular purchaser paying less per unit than what everyone else pays. A "volume discount" is a "price decrease based on a large-quantity purchase"; if you buy more than the average purchaser, you pay less per unit. *Volume Discount*, Black's Law Dictionary (11th ed. 2019). A "prompt pay discount" allows buyers in industries where buyers typically do not pay upfront to pay less per unit if they do. *See* 3 Health Care Law Sourcebook § 447.502. "Rebates" are per-unit "discount[s]" "given retrospectively." *Rebate*, Oxford English Dictionary Online, https://tinyurl.com/f68t44hv. A "free good contingent on any purchase requirement" gives buyers a right to obtain additional goods for no additional charge, reducing the price paid per item. A "chargeback" in this context refers not to reversing a transaction that a buyer did not actually intend, *see Charge-back*, Black's Law Dictionary (11th ed. 2019), but to the mechanism by which a manufacturer reimburses a distributor for a price concession the distributor extends to an end-purchaser on the manufacturer's behalf. *See* Cong. Budget Off., Pub. No. 2703, *Prescription Drug Pricing in the Private Sector* 13 n.27 (Jan. 2007), https://tinyurl.com/jnj4jdpp.[7] Finally, "cash discount" can mean one of two things—a discount for paying in cash,[8] or a discount for paying upfront (regardless of payment method)[9]—both of which reduce the price paid per item.

[7] *See generally City of Providence v. Barr*, 954 F.3d 23, 34 (1st Cir. 2020) ("[W]ords grouped in a list should be given related meaning." (citation omitted)).
[8] *See, e.g.*, 15 U.S.C. § 1666f.
[9] *See Cash Discount*, Black's Law Dictionary (11th ed. 2019) ("A reduction from the stated price if the bill is paid on or before a specified date."), *Cash Discount*, American Heritage Dictionary (5th ed. 2022) ("A reduction in the price of an item for sale allowed if payment is made within a stipulated period."); *Cash Discount*, Webster's Third New International Dictionary (1968) ("[A] discount granted in consideration of immediate payment or payment within a prescribed time."); *see also Eby-Brown Co. v. Wis. Dep't of Agric., Trade & Consumer Prot.*, 213 F. Supp. 2d 993, 1008 (W.D. Wis. 2001) (citing similar definitions).

Again, charging a single cash-or-credit price is the opposite of a price concession. And reimbursing the fees that financial institutions actually charge distributors to process credit card transactions is likewise nothing like a price concession. Rather, it is a reimbursement of actual expenses that facilitates maintaining a single cash-or-credit price charged to all doctors without concessions. Indeed, because processing credit card transaction fees actually costs money (just like shipping goods from point A to point B), reimbursing that cost simply ensures that physicians pay *the same price* no matter what payment method they use—as Plaintiffs themselves acknowledge. *See, e.g.*, Compl. ¶ 2 (alleging that Regeneron "pa[ys]" these "fees so that doctors and retina practices that purchase[] Eylea c[an] use credit cards at no additional cost"); *id.* ¶ 59 (similar). That readily explains why Congress did not include reimbursing credit card processing fees on the list—and it confirms why CMS's only regulatory intervention was to make clear that bona fide service fees should not be included in ASP, *infra* pp. 8, 21. After all, conduct that results in a single cash-or-credit price that customers pay regardless of payment method is not a concession that results in some purchasers paying a lower price based on payment method.

Perhaps recognizing this fundamental difficulty with their theory, Plaintiffs obliquely suggest that reimbursing credit card processing fees incurred by a distributor is akin to a "cash discount." *See* Compl. ¶¶ 75-76. But it is telling that Plaintiffs cannot actually bring themselves to assert that Regeneron offered a "cash discount." In reality, a credit card processing fee is an expense, not a price concession or anything like it, and charging customers a single cash-or-credit price is literally the opposite of a cash discount. *See Texaco, Inc. v. Hughes*, 572 F. Supp. 1, 7 (D. Md. 1982) (holding that credit card processing fees "are not cash discounts" under the Cash

Discount Act, but rather are "an 'extra' charge *imposed*" by financial institutions (emphasis added)).[10]

C. Had Congress Wanted The Manufacturer's Average Sales Price To Account For Credit Card Rewards Earned By Purchasers, It Would Have Said So.

Finally, Plaintiffs try to salvage their allegations by suggesting that credit card reward programs change the calculus. *See, e.g.*, Compl. ¶¶ 2, 10, 54. They do not. The fact that financial institutions provide a service that is costly to sellers yet can result in rewards for purchasers has nothing to do with Regeneron (or distributors). Credit card rewards are beyond the control of a seller of a good, whether that seller is a pharmaceutical manufacturer or a pizza parlor. And the extent of the rewards vary from purchaser to purchaser. One customer may receive travel rewards, another 1% cash-back, another 2% cash-back but only on certain purchases, and another may earn nothing at all. When a pizza parlor charges a single cash-or-credit price, no one thinks they are, in fact, offering customers a range of different discounts just by allowing customers to pay with plastic. That is because, whatever the arrangement between customers and their credit card providers, the pizza parlor is not charging more than one price. The reality is no different with doctors purchasing EYLEA, and nothing in the ASP statute even remotely suggests that manufacturers must include in ASP the rewards that *some other party* offers for using that third party's product as a payment device. For good reason, as ASP is a calculation of a *manufacturer's* average *sales* price, and manufacturers neither offer credit card rewards in their sales nor have much (if any) visibility into who may or may not receive them and in what amounts.

[10] Furthermore, all the claims identified in the United States' complaint are from physicians in Massachusetts, *see* Compl. ¶ 131, which, as noted above, prohibits passing on credit card transaction fees to consumers. Not imposing an upcharge on customers *that is legally prohibited* cannot under any under any circumstance be considered a "discount," let alone a "cash discount."

It is no surprise, then, that not even Plaintiffs seem to think that merely allowing doctors to use credit cards (and receive rewards) to pay a single cash-or-credit price alone constitutes a price concession without regard to whether the transaction fees are reimbursed. And reimbursing fees actually incurred by distributors is not a price concession to the doctors. The amount of the reimbursed fees is different from the amount of the rewards earned by doctors—and neither amount represents a price concession that must be included in ASP.

II. Credit Card Processing Fees Need Not Be Included In ASP For The Independent Reason That They Are Bona Fide Services Fees.

Plaintiffs' claims fail for yet another independent reason: Credit card processing fees are textbook bona fide service fees, such that they "are not considered price concessions." 42 C.F.R. § 414.804(a)(2)(ii). Under 42 C.F.R. § 414.802, "bona fide service fees" are "fees paid by a manufacturer to an entity, that [1] represent fair market value for a [2] bona fide, [3] itemized service [4] actually performed on behalf of the manufacturer [5] that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that [6] are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug." Credit card processing fees plainly and unsurprisingly meet each of those criteria.

1. Fair Market Value. Plaintiffs do not dispute that when Regeneron reimburses credit card processing fees incurred by its distributors, Regeneron pays fair market value. Nor could they: Regeneron pays the "Actual Cost" of such fees. *See, e.g.*, Compl. Ex. 2 at 32.

2. Bona Fide Service. Plaintiffs allege that the service at issue is "pay[ing] distributors to accept credit cards without charging customers more" and contend that *that* fee is not bona fide. Compl. ¶ 95. That argument is doubly wrong. The actual service at issue is the one that financial institutions perform when they securely process credit card transactions. And both that service and the separate services Regeneron pays its distributors to perform are clearly bona fide.

As the United States' exhibits show, Regeneron pays its distributors a set distribution fee for services that include account setup, invoicing, and order processing. *See* Compl. Ex. 2 at 28. This distribution fee covers the services that Regeneron's distributors perform when they accept credit cards, including setting up the customer's account and billing the customer when they use a credit card. And *Plaintiffs agree* that these are all "bona fide distribution services." Compl. ¶ 94.

Regeneron separately pays distributors the "Actual Cost" of "Credit card fees *charged by bank/processing company*." Compl. Ex. 2 at 32 (emphasis added). Plaintiffs do not dispute that credit card processing is a bona fide service. Nor could they. The FDIC and IRS have consistently acknowledged the indisputable reality that banks and other financial institutions provide a valuable "service" to merchants and customers alike when they process credit card transactions.[11] Indeed, if financial institutions were not providing a valuable service when buyers swiped, then no one would pay the fee they impose. But financial institutions do charge to process credit card transactions for the simple reason that securely and expeditiously processing credit card transactions is enormously complicated, and enormously consequential for all parties. *Supra* p. 6.

Plaintiffs nonetheless seem to argue that these fees are not bona fide because *distributors* do not perform the service. *See* Compl. ¶ 94. But nothing in § 414.802 says that services must be performed by the distributor. Nor would such a limitation make sense. Bona fide services may be provided by many different entities, including the shippers that pick up EYLEA from a distributor and take it to a physician. *See* Compl. Ex. 2 at 34. Indeed, Plaintiffs *agree* that the distribution fee Regeneron pays distributors is bona fide, Compl. ¶ 94, and that fee *includes* shipping by

[11] As the FDIC has explained, credit card processing involves significant risk for financial institutions, including credit and liquidity risk. *See* FDIC Manual, *supra*, at 174. The IRS has likewise described card processing fees as fees that are charged "in connection with the services performed" by financial institutions. *See* Rev. Rul. 78-40, 1978-1 C.B. 136, at *1 (1978).

"express carrier"—a service provided by a third-party shipping company, not the distributor. Compl. Ex. 2 at 35 (Ex. E at 2(b)). There is no basis to distinguish between third-party-imposed shipping fees and third-party-imposed credit card processing fees. When Regeneron reimburses its distributors for the credit card processing fees they incur, it is paying for a bona fide service no less than when it reimburses distributors for other third-party-imposed costs like shipping fees.

3. Itemized. Plaintiffs do not dispute that credit card processing fees are itemized. That is because they indisputably are itemized. *See, e.g.*, Compl. Ex. 14 at 3 (invoice itemizing credit card processing fees).

4. Actually Performed on Behalf of the Manufacturer. Plaintiffs allege that the "service" of "acceptance of credit cards without a fee" was "performed on behalf of customers—not Regeneron." Compl. ¶¶ 96-97. Again, that is not a service Regeneron pays for; the service at issue is credit card processing. And that service is unquestionably performed by financial institutions for distributors on Regeneron's behalf.[12]

Accepting Plaintiffs' contrary theory would mean that even ordinary shipping fees are not "on behalf of the manufacturer." After all, Regeneron's distributors arrange for third-party shipping companies to take EYLEA from their warehouses and deliver it to physicians, and the shipping companies charge for that service. *See* Compl. Ex. 2 at 35 (Ex. E at 2(b)). There is no difference between that service (which enables Regeneron to get its products to customers) and the service financial institutions perform by processing credit card transactions involving EYLEA. Both are on Regeneron's behalf *because they enable Regeneron to get its products to customers.*

[12] To the extent Plaintiffs are arguing that any service that benefits Regeneron's customers is not "on behalf" of Regeneron, that is inconsistent with 42 C.F.R. § 414.802 (and common sense). The regulation asks only whether a service is performed on Regeneron's behalf, not whether it also benefits Regeneron's customers. That makes sense, as nearly any service performed in the process of getting a product to end-purchasers benefits both the manufacturer and its ultimate customers.

5. That The Manufacturer Would Otherwise Perform (Or Contract For). Plaintiffs allege that "Regeneron knew it did not have to perform or contract for the 'service' of causing distributors to waive costs to customers for using credit cards in order for Eylea to be distributed." Compl. ¶ 101. That again confuses the service at issue. Credit card processing is not free. So as long as Regeneron did not want to impose a surcharge for accepting credit cards, either Regeneron or its distributors would have to cover the processing fee as an expense (just as countless merchants across the country do). And since the distributors are the ones actually processing the transactions and incurring the expense on Regeneron's behalf, it makes perfect sense that Regeneron reimburses these expenses. But they are a quintessential expense that—absent the distributor's role—Regeneron would otherwise contract for.

The United States attached to its complaint a document showing that physicians purchased Lucentis, a competing drug, directly from the manufacturer (Genentech) *using credit cards*—showing that credit card processing is a crucial service that manufacturers contract for in this industry. *See* Compl. Ex. 38 at 23. Plaintiffs allege, moreover, that doctors would have continued to "use credit cards for their Eylea purchases" *even if* they had to pay a surcharge reflecting the cost of credit card processing, Compl. ¶ 101, underscoring that Regeneron would have contracted for credit card processing *even if* it sold directly to doctors and charged a surcharge for credit card transactions. Plaintiffs thus have not alleged—and could not plausibly allege—that Regeneron would not have contracted with financial institutions to provide credit card processing if Regeneron's distributors did not do so on Regeneron's behalf.

6. Not Passed On. CMS has directed that "the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity." 71 Fed. Reg. at 69,669. Plaintiffs do not allege, let alone point to any evidence,

that credit card processing fees were indeed passed on to physicians. Nor could they: The whole thrust of their claim is that Regeneron's reimbursement practice ensured that the fees *were not* passed on.

Plaintiffs nonetheless assert that "Regeneron knew its payments were passed on to customers in two ways: (1) the lower, subsidized prices customers paid when they used credit cards to purchase Eylea from distributors, and (2) the 'cash back' and credit card rewards Eylea customers received from those purchases." Compl. ¶ 104. That argument is contrary to the text of the regulation, which makes clear that the relevant question is whether the bona fide service fees are "passed on in whole or in part to a client or customer of an entity." 42 C.F.R. § 414.802. The question is *not* whether customers received some other benefit—i.e., paid "lower, subsidized prices"[13] (which they did not) or received "'cash back' and credit card rewards"—as a result of Regeneron's reimbursement practice. *Contra* Compl. ¶ 104. The question is whether the credit card processing fee *itself* was passed on to doctors. 42 C.F.R. § 414.802; *see, e.g., United States ex rel. Streck v. Bristol-Myers Squibb Co.*, 2018 WL 6300578, at *10 (E.D. Pa. Nov. 29, 2018) (analyzing whether the "fees at issue" were passed on). And here, it indisputably was not.

Once again, Plaintiffs appear to think there is something problematic about the fact that many physicians affirmatively prefer to use credit cards and that reimbursing processing fees incurred by distributors facilitates that preference. But the same could be said of any number of services and the bona fide fees that cover them. Doctors also prefer to get shipping at no additional charge—and a distributor that incurs actual expenses in supplying that service may be reimbursed by manufacturers without triggering a requirement that the manufacturer treat the costs of shipping

[13] In all events, and as explained at length above, Plaintiffs have not plausibly alleged that physicians who paid with a credit card paid a lower price. Plaintiffs themselves allege that Regeneron's distributors charged physicians the *same price* regardless of payment method.

as price concessions that must be included in (i.e., subtracted from) ASP. The result is no different when the reimbursed fees are credit card transaction fees, rather than shipping fees.

Unable to distinguish third-party-imposed credit card transaction fees from third-party-imposed shipping fees (and other textbook bona fide service fees), Plaintiffs insist that physicians benefit in a material and distinct way when they use credit cards to purchase prescription drugs. But this is neither secret nor nefarious—and it has nothing to do with price concessions or whether paying the cost of processing credit card transactions are bona fide service fees. Every day, millions of Americans seek reimbursement for expenses paid for by credit card without accounting for rewards or cash-back, and no one thinks that they are all committing mail or wire fraud. Yet if this Court were to hold that Regeneron *is* committing fraud by failing to account for credit card reward points secured by physicians in transactions with their credit card company (in which Regeneron has no direct involvement), then everyone who *is* a party to a credit card transaction and later seeks reimbursement for their expenses without accounting for any credit card rewards they may have received is a fraudster *a fortiori*. Accepting Plaintiffs' view would thus create traps for the unwary and put millions of Americans in legal jeopardy.[14]

If Congress wanted to deviate from the general understanding that businesses may set a single price for all purchasers, regardless of the form of payment, it could and should have said so. But nowhere in the ASP statute does Congress require manufacturers to account for fees charged by credit card companies or the rewards offered by those companies—things that have nothing to do with manufacturers (or their distributors). For the government to treat that unobjectionable practice as the basis for a massive FCA recovery is unjustified and fundamentally unfair. *See*

[14] To be sure, the ASP formula may be more complicated than the typical employer-reimbursement scheme. But that just underscores the necessity of providing clear guidance before deeming fraudulent (and the basis for essentially punitive liability) a common societal practice.

Credit Suisse Sec. (USA) LLC v. Billing, 551 U.S. 264, 279 (2007) (rejecting treble-damages liability where "a fine, complex, detailed line separates activity that the [government] permits or encourages … from activity that the [government] must (and inevitably will) forbid"). The government had every opportunity to provide clear guidance on this matter. Having failed to do so, it should not be allowed to ambush Regeneron (or other manufacturers) with the theory that a common and unobjectionable practice is fraudulent.

In summary, when Regeneron reimburses credit card processing fees incurred by its distributors, it is not offering a discount or anything like it. It is simply *paying the cost of a service* performed by financial institutions that process credit card transactions. *Supra* pp. 6, 21-22. Regeneron reimburses credit card processing fees at cost, *see* Compl. Ex. 2 at 32, making distributors whole for a fee they incur when distributing Regeneron's products. Regeneron pays for many other services that are performed by distributors or third parties, ranging from account setup to returns to shipping. *Supra* pp. 5-6, 22-23. Credit card processing fees are no different, and are not price concessions.

III. Regeneron's Interpretation Was At The Very Least Reasonable—And In This Context, A Reasonable Interpretation Cannot Be False Or Fraudulent.

The FCA does not impose liability unless a claim is "false or fraudulent." 31 U.S.C. § 3729(a)(1). And because something is neither false nor fraudulent unless it is untrue, the First Circuit (like many courts) has held that "statements as to conclusions about which reasonable minds may differ cannot be false," full stop, and thus cannot give rise to FCA liability. *Brigham & Women's Hosp.*, 678 F.3d at 87 (citation omitted). That standard applies here and makes this an easy case. Even if (contrary to all the arguments above) the Court disagrees with Regeneron about the *best* reading of the ASP statute and corresponding regulations, Regeneron's interpretation was

and is at the very least a reasonable one. That is not only all that is required generally, but is all the government asked of manufacturers here. Plaintiffs fail to state a claim for this reason too.[15]

The FCA does "not define what makes a claim 'false' or 'fraudulent.'" *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 187 (2016). With respect to the term "false," this Court must give it its ordinary meaning: "Untrue." *False*, Black's Law Dictionary (11th ed. 2019); *see also False Claim*, Black's Law Dictionary (11th ed. 2019) ("[a]n assertion or statement that is untrue"). As for false's companion term, "fraudulent," the Supreme Court has held that it "is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud"—which requires either "express falsehoods" or "misleading omissions." *Escobar*, 579 U.S. at 187. For a person to be liable under the FCA, then, a claim must either expressly or impliedly state something untrue. *Id.*

The First Circuit, consistent with these principles, has held that "statements as to conclusions about which reasonable minds may differ cannot be false" and thus cannot give rise to FCA liability. *Brigham & Women's Hosp.*, 678 F.3d at 87 (quoting *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000)); *see Roby*, 100 F. Supp. 2d at 626 (stating that (i) "flawed reasoning" does not amount to falsity, and (ii) a reasonable interpretation of a "term that is incapable of precise definition" is not false) (citations omitted)); *see also United States v. Rowe*, 144 F.3d 15, 21 (1st Cir. 1998) (discussing "the rule that, in a false statement prosecution, an answer to a question is not fraudulent if there is an objectively reasonable interpretation of the question under which the answer is not even false"). After all, if reasonable minds may differ on

[15] *See United States v. Prigmore*, 243 F.3d 1, 18 (1st Cir. 2001) ("the judge, and not the jury, must resolve" disputes over the "reasonableness of a defendant's understanding of applicable law").

whether a law requires both X and Y or just X, then doing just X and certifying compliance with the law is not untrue.

That principle applies *a fortiori* here, where the regulatory regime affirmatively invites manufacturers to make reasonable judgments on matters where the regulators have refused to provide clarity.[16] CMS has instructed that, "in the absence of specific guidance," the "manufacturer may make reasonable assumptions in its calculations of ASP." 71 Fed. Reg. at 49,000; *see supra* pp. 9-10. And as one might expect given the agency's overall lack of guidance in this area and laissez faire approach to ASP, *CMS has not provided any specific guidance* regarding credit card processing fees (or anything like them). *Supra* pp. 8-9. Regeneron was thus instructed to (and did) make reasonable assumptions in calculating EYLEA's ASP, including about whether credit card processing fees should be treated as bona fide service fees. *See* Compl. ¶ 109.[17]

[16] The Fourth, Seventh, and Eleventh Circuits all agree with the First Circuit that certifying compliance based on a reasonable interpretation cannot form the basis of FCA liability. *See, e.g.*, *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008); *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011); *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1298 (11th Cir. 2019). The Third, Ninth, and Tenth Circuits have taken a different approach, allowing FCA liability even when a defendant adopted a reasonable view of an ambiguous legal obligation. *See, e.g.*, *United States v. Care Alts.*, 952 F.3d 89, 91 (3d Cir. 2020); *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1119, 1122 (9th Cir. 2020); *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742-43 (10th Cir. 2018). But no court to our knowledge has ever held that a statute or regulation expressly inviting regulated parties to make reasonable judgment calls can give rise to FCA liability if a court later determines that the best reading of the statute differs from the reasonable interpretation adopted by the regulated party.

[17] Furthermore, CMS requires manufacturer ASP submissions to certify only that ASP is "true, complete, and current to the best of [the certifier's] knowledge and belief and made in good faith." 69 Fed. Reg. at 17,940; *supra* p. 11. That raises another problem with Plaintiffs' claims, as nothing in either complaint establishes fraud sufficient for Rule 9(b) as to that certification. *See Lawton*, 842 F.3d at 132 (affirming Rule 9(b) dismissal where "arguments proceed[ed] more by insinuation than any factual or statistical evidence that would strengthen the inference of fraud beyond possibility" (citation omitted)); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 717 (N.D. Tex. 2011) (similar).

Indeed, the closest CMS has come to offering meaningful guidance in this area is articulating its desire for the category of bona fide service fees to sweep broadly. As explained above, there is an endemic and widely acknowledged "lack of clear guidance from CMS on issues related to the treatment of sales and discounts that affect ASP calculations." 2022 HHS-OIG Report at 11. CMS has not shied away from this reality. Instead, it has tried to justify its failure to provide clarity in part by explaining that *it does not want to unduly "limit*[]" *the types of fee arrangements that may qualify as bona fide service fees*. *See, e.g.*, 71 Fed. Reg. at 69,668 ("Although some commenters provided us with general information on what they would view to be bona fide services, *to avoid inadvertently limiting the scope* of what could constitute a bona fide service, we will not establish a list of 'bona fide services' at this time." (emphasis added)); 72 Fed. Reg. at 39,184 (reiterating that "[p]roviding a list of types of bona fide service fee payments *could limit the scope* of what constitutes a bona fide service" (emphasis added)). Against that backdrop, it would make no sense—and flout bedrock principles of fair notice—to hold that Regeneron needed to adopt a narrow interpretation of what constitutes a bona fide service fee, and now faces punishing liability for (at worst) misreading the tea leaves.

That is all the more true given that ASP is not the only consideration when it comes to determining whether something constitutes a bona fide service fee. EYLEA is both a Medicare drug and a Medicaid drug. The two programs have different reimbursement regimes. Whereas the federal government reimburses doctors directly under Medicare, Medicaid requires manufacturers to pay rebates to the states (which in turn share those rebates with the federal government) based on a metric known as Average Manufacturer Price ("AMP"). 42 U.S.C. § 1396r-8(c). As a result, the higher the AMP, the more money the states and the federal

government receive. But that is the opposite of ASP; the higher the ASP, the more money the federal government must *pay out*.

That creates a quandary, because as with ASP, bona fide service fees are not included in AMP. *See* 42 C.F.R. § 447.504(c)(14), (e)(5). Had Regeneron concluded that credit card processing fees are not bona fide service fees (as Plaintiffs claim it should have), it would have needed to include them in EYLEA's AMP as well—lowering AMP, which would have *cost Plaintiffs money* on the Medicaid side. *See* 42 U.S.C. § 1396r-8(a)(1), (c)(1)(A), (k)(1)(B)(i)(II); 42 C.F.R. §§ 414.802, 447.502, 447.504(c)(14), (e)(5). There is thus no clearly "safe" treatment of credit card processing fees. Indeed, had Regeneron included credit card processing fees in ASP (on Plaintiffs' theory that they are not bona fide service fees), then it almost certainly would have been sued from the other end of the stick for supposedly under-reporting EYLEA's AMP. Indeed, *qui tam* relators have sued manufacturers under the FCA on exactly that theory. *See*, *e.g.*, *Streck*, 2018 WL 6300578, at *2-3. Given that regulatory reality, it is particularly noteworthy that the vast majority of states did not join this suit; their Medicaid programs may well have benefited from the treatment of credit card processing fees as bona fide service fees. In this situation, not only does the reasonable-assumptions regime make sense, but the notion that Regeneron was so unreasonable to justify imposing essentially punitive FCA liability does not pass the straight-face test.

In all events, this Court need not wade into multiple regulatory thickets. There is simply no basis to hold that Regeneron acted unreasonably—and can be subject to crippling liability—when it took CMS at its word and made reasonable assumptions as to what makes something a bona fide service fee. Any other conclusion would transform the reasonable-assumptions regime that CMS imposed upon manufacturers (despite their repeated requests for guidance) into a "snare[] for the unwary," violating bedrock principles of fair notice and due process. *United States*

v. Sun-Diamond Growers of Cal., 526 U.S. 398, 411 (1999). Put differently, where a federal regulator itself asks for only reasonable interpretations of a law, a regulated entity's reasonable interpretation does not become false just because a different agency, or even a court, disagrees with it many years or decades later. Where an agency has invited regulated entities to make reasonable assumptions about the metes and bounds of complicated laws and regulations, it would turn basic constitutional principles upside down to make a party's objectively reasonable construction arguably correct one day, but then "false"—and thus the basis of enormous liability—the next.

One final note on this issue. Although Plaintiffs try to create a linkage between them, this case is very different from the Average Wholesale Price ("AWP") litigation, where manufacturers argued they had "*carte blanche* to publish sky-high prices unmoored from the acquisition costs of providers," leading to "absurd results." *In re Pharm. Indus. AWP Litig.*, 478 F. Supp. 2d 164, 173 (D. Mass. 2007). Unlike in the *AWP* litigation, where the statute did not provide manufacturers any guidance about the meaning of AWP, here, Congress has created a detailed statutory scheme—specifying precisely which price concessions it wants manufacturers to include in ASP and granting CMS (and it alone) authority to add any "other price concessions" to the list, 42 U.S.C. § 1395w-3(c)(3). Regeneron has reasonably interpreted this scheme. *Supra* pp. 11-12, 29. The dynamic here, then, is the opposite of the situation in the *AWP* litigation. For one thing, Plaintiffs are not alleging—and cannot allege—that EYLEA's reported ASP is unmoored from the price purchasers actually pay. And in stark contrast to *AWP*, it is Plaintiffs' position here that leads to absurd results. If Plaintiffs are right, then Regeneron will be on the hook for colossal damages and penalties based on an interpretation of the law that CMS refused to provide for decades and is only articulated for the first time in an enforcement action brought by a different agency against a single manufacturer.

There is no reason to go down that constitutionally dubious road—and every reason not to. Especially given CMS's direction to make reasonable assumptions, the question for purposes of falsity here is not whether Regeneron or Plaintiffs has the better interpretation of the ASP statute and the corresponding regulations; it is whether "reasonable minds may differ" with Plaintiffs' view that credit card processing fees must be included in ASP. *See Brigham & Women's Hosp.*, 678 F.3d at 87 (citation omitted). Reasonable minds plainly may differ. *Supra* pp. 27-28. Because Regeneron did exactly what CMS asked of it, adopting and acting pursuant to interpretations of the ASP statute and the bona fide service fee regulations that were at the very least reasonable (if not correct, *supra* pp. 20-27), Plaintiffs' allegations fail as a matter of law.

IV. Plaintiffs Have Not Plausibly Alleged Anything False Or Fraudulent About Any "Claims" Submitted To The Government.

There is yet another problem with Plaintiffs' claims. While previous versions of the statute were worded differently, the FCA now imposes liability on "any person who … (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1). The statute's plain text thus requires that, "for a false statement to be actionable under either subsection of the FCA, *it must be made as part of a false or fraudulent claim*." *Grant*, 912 F.3d at 196 (emphasis added); *accord, e.g.*, *Booker*, 9 F. Supp. 3d at 53 ("While underlying fraudulent conduct … may constitute 'false statement[s]' for purposes of § 3729(a)(1)(B), such conduct does not in and of itself establish the 'false or fraudulent claim' required for liability under both §§ 3729(a)(1)(A) and (B)."). And the FCA defines the term "claim" as "any request or demand, whether under a contract or otherwise, for money or property" that "is presented to an officer, employee, or agent of the United States" or a contractor. 31 U.S.C. § 3729(b)(2). So, to establish liability under either § 3729(a)(1)(A) [Count I of the United States'

complaint] or § 3729(a)(1)(B) [Count II of the United States' complaint], there must be something false or fraudulent *in an actual* "*claim*," i.e., in a demand for payment presented to the government.

That straightforward textual requirement defeats Plaintiffs' claims. Plaintiffs allege that Regeneron miscalculated EYLEA's ASP and thus submitted "false" quarterly ASP reports to CMS. *See, e.g.*, Compl. ¶¶ 11-14. That is wrong for all the reasons explained above. But even assuming otherwise *arguendo*, Plaintiffs' claims still fail, because quarterly ASP submissions do not "request … money or property" from the government. *See* 31 U.S.C. § 3729(b)(2). Manufacturers submit quarterly ASP submissions to comply with federal regulations, not to seek payment. *See* Compl. ¶ 11; *see also* 42 U.S.C. §§ 1395w-3a(f)(1), 1396r-8(b)(3).

The only actual "claims" here are the ones ophthalmologists submit seeking reimbursement for EYLEA. *Supra* p. 7; *see* Compl. ¶¶ 21-24. But Plaintiffs have not alleged anything false or fraudulent about any of *those* claims—because there is nothing false or fraudulent about them. Plaintiffs' FCA claims therefore fail regardless of how this Court resolves the falsity question.

Plaintiffs may respond by pointing to *Escobar* and the so-called "implied certification theory" of FCA liability. But that theory still demands *an actual* "*claim*" that impliedly (but falsely) certifies compliance with a legal obligation. *Escobar* was clear on this point: For "the implied certification theory" to form the "basis for liability," at least "two conditions" must be met—"first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." 579 U.S. at 190. Neither condition is satisfied here. Regeneron's ASP submissions do not "request payment." And while physicians' reimbursement

requests obviously do, they just as obviously do *not* certify compliance with the ASP statute when they seek reimbursement based on ASP. *Escobar* is thus no help to Plaintiffs.

Nor can Plaintiffs salvage their case by relying on a scheme-to-defraud theory. Plaintiffs suggest Regeneron adopted its practice of reimbursing credit card processing fees *not* to ensure that doctors paid the same price for EYLEA regardless of payment method, but to induce doctors to purchase and prescribe EYLEA instead of a competitor's product, and argue that Regeneron's failure to include those fees in calculating ASP cost the government money, adding up to a nefarious scheme. *See, e.g.*, Compl. ¶¶ 129, 132. All of that is nonsense. But even if Plaintiffs were right, that still would not support an FCA claim. The FCA "does not create a cause of action against all fraudulent conduct affecting the government." *Booker*, 9 F. Supp. 3d at 53 (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007)). Rather, "FCA liability attaches only to false *claims*." *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 124 (1st Cir. 2013).

To be sure, as the First Circuit noted in *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011), the Supreme Court stated in 1943 "that the language of the FCA 'indicate[d] a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud.'" *Id.* at 390 (quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943)). But "no legislation pursues its purposes at all costs." *Acosta v. Loc. Union 26, UNITE HERE*, 895 F.3d 141, 146 (1st Cir. 2018) (Souter, J.) (quoting *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (per curiam)). And in all events, the language of the FCA today is crystal clear that an actual false claim is required. *Supra* pp. 33-34. For that reason, "courts have routinely rejected litigants' attempts to use fraudulent *conduct* to

avoid the need to show false *claims*." *Booker*, 9 F. Supp. 3d at 53.[18] That includes the First Circuit, which holds that even where fraudulent practices induced third parties to submit claims for payment, the underlying fraud does not carry over to the claims themselves. *New York v. Amgen Inc.*, 652 F.3d 103, 111 (1st Cir. 2011). As a result, even a claim under § 3729(a)(1)(B) cannot prevail unless the "claim" the third party was fraudulently induced to submit is itself false or fraudulent. *Id.* And because Plaintiffs have not pleaded anything false or fraudulent about any actual "claim" within the meaning of § 3729(b)(2), there can be no FCA liability here.

V. Plaintiffs Have Not Plausibly Alleged Scienter.

The FCA's scienter requirement is "rigorous," *Escobar*, 579 U.S. at 192, with the "focus primarily on what [the defendant] thought and believed," *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 751 (2023). An FCA complaint must therefore "set forth specific facts that support an inference of fraud." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (citation omitted). Here, however, Plaintiffs have not plausibly alleged that Regeneron acted with actual knowledge, deliberate indifference, or reckless disregard of its legal obligations, as 31 U.S.C. § 3729(b)(1)(A) requires. While Plaintiffs *say* that "Regeneron knew its payments of credit card processing fees were price concessions" and not bona fide service fees, Compl. ¶ 90, nowhere do they plausibly plead any actual facts to support scienter.

That is because they cannot. Plaintiffs begin by alleging that Regeneron supposedly failed to analyze credit card processing fees "under the four-prong test" for determining whether something constitutes a bona fide service fee, and they invoke this supposed failure as evidence of scienter. *Id.* ¶ 109. But Plaintiffs admit that Regeneron concluded in 2016 that credit card

[18] This Court held in *In re Pharmaceutical Industry Average Wholesale Price Litigation* that "under California law," an FCA "claim itself need not be false but only be underpinned by fraud." 478 F. Supp. 2d at 172 (citation omitted). The text of the federal FCA, however, requires an actual false claim, as do the state FCA statutes on which Plaintiffs' claims are based.

processing fees *are* bona fide service fees, citing an internal Regeneron document. *See id.* That suffices to refute any suggestion that Regeneron "knew" that credit card processing fees are price concessions (and not bona fide service fees) that needed to be included in ASP, let alone that it had knowledge sufficient for FCA liability. And while Plaintiffs meekly claim that the document they cite lacks sufficient analysis, *see id.*, they do not (and could not) allege *either* that Regeneron's analysis was a sham *or* that the one cited document contained the entirety of Regeneron's analysis.

The rest of Plaintiffs' attempts to establish scienter fit the same pattern. While Plaintiffs cite various documents to try to create a cloud of smoke and support an inference of fire, their own allegations—and the very documents they collected in their investigation—pour cold water on their theory. For instance, Plaintiffs cite (Compl. ¶ 98) a 2018 Deloitte document marked "[d]raft for discussion purposes only" with the word "No" in a column labeled "Type of Service Could be BFSF [i.e., bona fide service fees]?" Compl. Ex. 42 at 21-23 (capitalization altered). But Plaintiffs do not allege that this was the final draft, that Deloitte in fact advised Regeneron that credit card processing fees are not bona fide service fees, or that Regeneron actually relied on any such (non-existent) recommendation. Indeed, Plaintiffs ignore that the very same document states that "Regeneron has concluded that the actual cost of the credit card fees is in-line with common industry terms and Regeneron would otherwise incur these costs. Therefore, Regeneron has concluded that the credit card fees are excludable from government pricing calculations including the calculation of ASP." *Id.* at 23-24. After a nearly three-year federal investigation, including interviews of multiple Deloitte employees, Plaintiffs' failure to cite the statements or testimony they already obtained from Deloitte employees speaks volumes.

Plaintiffs' remaining scienter allegations are no less problematic. Plaintiffs allege that Regeneron "did not perform any BFSF analyses" before Regeneron employee Alicia Pantaleo

approved Regeneron's ASP submission, thus (they say) acting in reckless disregard of its obligations. Compl. ¶ 110. To try to substantiate that claim, Plaintiffs note that, "in February 2018, Ms. Pantaleo asked Deloitte, Regeneron's consultant, 'did we ever do anything on credit card fees to substantiate that they were BFSF?'" *Id.* ¶ 111. But asking a question about whether X or Y has happened is (obviously) not an admission that X or Y did not happen—and all the cited email reflects is that Ms. Pantaleo wanted to know whether such an analysis had occurred.

Plaintiffs have thus failed to plausibly plead scienter. Indeed, despite investigating this issue for *years*, interviewing multiple Regeneron and third-party witnesses (including Deloitte employees), and attaching thousands of pages of documents to their pleadings, Plaintiffs do not meet the most basic scienter requirement: a plausible allegation "at least one individual within" Regeneron "acted knowingly" (as opposed to reasonably). *United States ex rel. Banigan v. Organon USA Inc.*, 2016 WL 10704126, at *5 (D. Mass. Aug. 23, 2016) ("Courts within the First Circuit require at least one individual within a corporate entity to have acted knowingly …."); *see, e.g.*, *United States v. Regeneron Pharms., Inc.*, 2023 WL 7016900, at *14 n.19 (D. Mass. Oct. 25, 2023) ("For purposes of establishing scienter under the FCA, … the 'collective knowledge' doctrine does not apply."). The only individual Plaintiffs mention with respect to their (scarce) scienter allegations is Ms. Pantaleo—and it should go without saying that a government plaintiff does not plausibly plead scienter sufficient to impose essentially punitive liability based on a single email asking what analysis Regeneron has done. Plaintiffs' threadbare allegations of scienter fail.

VI. The Court Should Dismiss The Intervening States' Claims Too.

The Court should dismiss the Intervening States' claims for all of the reasons stated above. The Intervening States are proceeding under state FCA statutes that are interpreted consistently

with the federal FCA in all material respects.[19] As a result, if this Court dismisses the federal claims, then it should dismiss the state FCA claims too for the same reasons.

A few of the Intervening States allege supposed distinctions between their claims and the United States'. Those alleged distinctions are overblown, and none changes the outcome.

For example, Texas asserts that the Texas Medicaid Fraud Prevention Act ("TMFPA") differs from the FCA because it "defines 'unlawful acts' that are actionable" (as opposed to just the submission of a false claim) and "permits the state to recover civil remedies and civil penalties rather than 'damages.'" State Compl. ¶ 96 (citation omitted). Neither distinction matters. Regeneron did not commit any unlawful act; it properly calculated ASP, in accordance with the plain text of the ASP statute and CMS's instruction to make reasonable assumptions. *Supra* pp. 13-28. That Texas may recover penalties for unlawful acts is therefore irrelevant. Texas acknowledges that "the TMFPA and federal FCA share similar objectives," State Compl. ¶ 96, and the Texas Supreme Court has likewise "described the TMFPA as analogous to the FCA in 'aim and tactic.'" *United States ex rel. Young v. Kindred Healthcare, Inc.*, 2022 WL 126486, at *4 (W.D. Tex. Jan. 13, 2022) (citation omitted), *report and recommendation adopted*, 2022 WL 1126041 (W.D. Tex. Feb. 8, 2022). Texas's claims thus rise and fall with the United States'.

In the same manner, Washington has brought a conspiracy claim, alleging that Regeneron "conspired to commit violations of the Washington Medicaid Fraud False Claims Act." State Compl. ¶ 192. But Washington "does not allege any facts as to (1) who the co-conspirators are, (2) when or where they entered into an agreement, or (3) what overt acts they took in furtherance

[19] *See, e.g.*, *Mazik v. Kaiser Permanente, Inc.*, 2024 WL 584162, at *11-12 & n.14 (E.D. Cal. Feb. 13, 2024) (Colorado, Georgia, Washington); *United States ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173, 179 & n.2 (4th Cir. 2022) (North Carolina); *United States v. Wal-Mart Stores E., LP*, 858 F. App'x 876, 880-81 (6th Cir. 2021) (Michigan); *United States ex rel. Rahimi v. Zydus Pharms. (USA), Inc.*, 2017 WL 1503986, at *12 (D.N.J. Apr. 26, 2017) (Texas).

of the conspiracy"—which means that this claim too must be dismissed. *United States ex rel. Leysock v. Forest Lab'ys, Inc.*, 55 F. Supp. 3d 210, 221 (D. Mass. 2014); *see also United States ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 270 (D. Mass. 2015) ("[C]onspiracy cannot be between the corporation and its officers and employees."). That claim, therefore, fails as well.

VII. Plaintiffs' Unjust Enrichment Claims Fail As A Matter Of Law.

The United States and the Intervening States allege unjust enrichment claims in addition to their FCA and state FCA claims. These claims all fail because each Plaintiff has an adequate remedy at law—the FCA and its state analogues—and "a party with an adequate remedy at law cannot claim unjust enrichment." *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 16 (1st Cir. 2017). Judges in this District "routinely dismiss[] unjust-enrichment claims" when brought as a companion to an FCA suit. *E.g., United States v. Regeneron Pharms., Inc.*, 2023 WL 6296393, at *14 (D. Mass. Sept. 27, 2023) (doing so, and collecting cases). This Court should do the same.

CONCLUSION

For the foregoing reasons, Plaintiffs' claims should be dismissed with prejudice.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the Court's CM/ECF system on July 18, 2024 and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

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